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EXAMINER

QUAN, ELIZABETH S

ART UNIT PAPER NUMBER

1743

DATE MAILED: 03/12/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,496

Applicant(s)

HALL ET AL.

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the locator hole or notch (whichever element (11) is not in the drawings of the immediate application) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to because it appears element (11) in the drawings of the immediate application is a locator hold in the form of notched tabs. The drawings point to the notch as the locator holes. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

1. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: attachment means, formed element.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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4. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Referring to claim 1, it is unclear how the lid provides a "means" or some element for developing a normal spring force. It appears the material of the lid is the factor in developing the spring force. The specification does not describe a lid provided with means to develop a spring force. From the drawings it appears the lid develops the spring force and not provide a means to develop a spring force to itself or some other object. It is confusing and redundant to recite **providing a means** for developing a normal spring force **by means** of a flexible curvilinear section of said lid. The means for developing the spring force in the lid or possessing the flexible curvilinear structure appears to be inherent to the flexibility of the material used in the lid. There appears to be no physical **means** for developing the spring force.
6. Referring to claims 1 and 9, it is unclear how the projections and apertures are integral to the cover. Are they somehow fused into one? Are they both part of the cover?
7. Claims 1 and 9 recite the limitation "cover plate" in the 5th and 10th lines, respectively. There is insufficient antecedent basis for this limitation in the claim. Are the projections and apertures on the lid or cover, meaning either the lid and/or uncompressed gasket?
8. Referring to claim 2, it appears the element (11) in the drawings of the immediate application is locator hole in the form of notched tabs. The drawings point to the notch as the locator holes.

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9. Referring to claim 3, it is unclear what the planar relationship is. Perhaps, the projections extend from and in the same plane as the side walls of the lid.

10. Referring to claim 5, it is unclear what is the geometrical relationship of the stacking lugs and stacking locators for aligning vertically one cover upon another cover in a stacked relationship.

11. Referring to claim 6, it is unclear what the formed element distal to the curvilinear section is. The formed element may be the side walls or stacking locator lugs.

Furthermore, it is unclear how the formed element is **distal** to the curvilinear section.

12. Referring to claim 7, it is unclear that how the gasket materials have low extractables in dimethyl sulfoxide and what it means.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1, 7 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.

Patent No. 6,436,351 to Gubernator et al.

Referring to claims 1, 7, Gubernator et al. disclose a cover, which is adapted for mechanical manipulation, for sealing and securing a multi-well plate (16) (see ABSTRACT; FIGS. 1A, 1B, and 2; COL. 1, lines 65-67; COL. 2, lines 1 and 2). The cover comprises a lid (26) dimensionally suited to covering a multi-

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well plate (16) and developing a normal spring force by a flexible curvilinear section of the lid (26) (see FIGS. 1A, 1B, and 2). Since both the immediate application and Gubernator et al. fabricate their lids from metal, it appears the lid would have a flexible curvilinear section. The term flexible is a relative term, and all materials have a certain degree of flexibility, such that the lid of Gubernator et al. would have a certain degree of flexibility in its curvilinear section. The lid (26) has a plurality of projections (28) and apertures (27,40,43) (see FIGS. 1A, 1B, and 2). Examiner has interpreted "projections and apertures integral to said cover plate" as both projections and apertures are on the cover plate. When the reaction system is not assembled or the lid is not pressed against the gasket and multi-well plate (16), the gasket (24), which is directly below the lid (26), is uncompressed (see FIGS. 1A, 1B, and 2). The gasket (156) may be made of thermoplastic polymers or elastomers, such as silicone rubber (see COL. 4, lines 60-62). The material having a durometer of Shore 15A or less or having low extractables in dimethyl sulfoxide is inherent to the materials used to make the gasket since the gasket (156) is made from thermoplastic polymers or elastomers, as disclosed in the specification. The lid (26) has at least two sidewalls that are approximately perpendicular to the curvilinear section of the lid (26) (see FIGS. 1A, 1B, and 2). The side walls have an attachment means in the form of projections or arms with a catch portion, which directly performs the function of attaching onto the notches (21) of the multi-well plate (16) (see FIGS. 1A, 1B, 2, 3A, and 3B). In the process of securing the lid (26) to the multi-well plate (16), the side walls of the lid (26) cause deformation of the curvilinear section of the lid

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(26), resulting in a normal spring force applied to the gasket (24) and compressing the gasket (24) against the upper planar surface of the multi-well plate (16) and effecting a seal (see COL. 4, lines 60-67; COL. 5, lines 1-12). The occurrence of deformation and application of normal spring force is inherent to the structure. It is noted that method limitations in device claims have no patentable weight in device claims if the prior art apparatus teaches all the structural limitations of the claim (MPEP 2114). Therefore, Gubernator et al. include all the limitations in claims 1 and 7.

15. Claims 1-3, 5-7, 9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,159,368 to Moring et al.

Referring to claims 1-3, 5-7, 9, Moring et al. disclose a cover (150), which is adapted for mechanical manipulation, for sealing and securing a multi-well plate (24) with approximately 3" x 5" footprint, uniform array of wells, and skirt extending around the perimeter of the multi-well plate (24) (see FIGS. 11-13; COL. 12, lines 6-11; COL. 27, lines 43-67; COL. 28, lines 1-67; COL. 29, lines 1-67; COL. 30, lines 1-53).

The cover (150) comprises a lid (154) dimensionally suited to covering a multi-well plate (24) and developing a normal spring force by a flexible curvilinear section of the lid (154) (see FIGS. 11-13). The cover (150) is described as comprised of a substantially rigid material thereby affording some degree of flexibility (see COL. 27, lines 66 and 67; COL. 28, lines 15-17). When the cover (150) is pressed down at opposing peripheral edge regions against corresponding regions of ridge (48) along the periphery of the multi-well plate

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(24), the annular region of each nodule (166) of gasket (156) is pressed into engagement with an upper lip (26b) of a respective well (26) (see FIGS. 11-13; COL. 27, lines 66 and 67; COL. 28, lines 1-4). To evenly distribute the downward force across gasket (156) integral beams (172,174) can extend laterally and/or longitudinally across the top surface of the lid (154), providing increased rigidity, which directs attention to the fact that there is some degree of flexibility (see COL. 28, lines 4-8). The gasket (156) is formed of a resiliently deformable material, such that, when the gasket (156) is compressed over openings (26a), a seal is formed (see COL. 28, lines 9-15). The gasket (156) may be made of thermoplastic polymers or elastomers, such as silicone, sodium polysulfide, polychloroprene, butadiene-styrene, and the like (see COL. 28, lines 11-15). The material having a durometer of Shore 15A or less or having low extractables in dimethyl sulfoxide is inherent to the materials used to make the gasket since the gasket (156) is made from thermoplastic polymers or elastomers, as disclosed in the specification. Since the lid (154) provides and distributes a downward force on the flexible gasket (156), the lid (154) along with its integral beams (172,174) must possess a certain degree of flexibility to impose the force and attach with the multi-well plate (24) (see FIGS. 11-13). Furthermore, the term flexible is a relative term, and all materials have a certain degree of flexibility, such that the lid of Moring et al. would have a certain degree of flexibility in its curvilinear section.

The lid (154) has a plurality of projections from the raised peripheries of the landing seats (212,213,221-224) to sleeves (211,214), integral beams

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(172,174), and projections (192) and apertures provided in the landing seats (212,213,221-224) and sleeves (211,214) (see FIGS. 11-13; COL. 29, lines 44-53). The projections (211-214,221-224) function as notched tabs with locator holes for gripping the cover (15) by mechanical methods (see FIGS. 11-13; COL. 29, lines 37-67; COL. 30, lines 1-23). According to Merriam-Webster Collegiate Dictionary, a tab is a short projecting device and a notch is a V-shaped indentation, a slit made to serve as a record, or a rounded indentation cut into the pages of a book on the edge opposite the spine. The projections (192,211-214,221-224) are short projecting devices, and projections (211,214) have notches or slits. It is noted that method limitations, such as function as notched tabs with locator holes for gripping of said cover by mechanical methods, in device claims have no patentable weight in device claims if the prior art apparatus teaches all the structural limitations of the claim (MPEP 2114). Examiner has interpreted “projections and apertures integral to said cover plate” as both projections and apertures are on the cover plate.

When the reaction system is not assembled or the lid is not pressed against the gasket and multi-well plate (24), the gasket (156), which is directly below the lid (154), is uncompressed (see FIGS. 11-13). The lid (154) has at least two sidewalls that are approximately perpendicular to the curvilinear section of the lid (154) (see FIGS. 11-13). The attachment means are inherent to the side walls of the lid (154) (see FIGS. 11-13). The attachment means may also be interpreted as projections or arms with a catch portion (184), which directly performs the function of attaching onto the circumferential side wall (24a) of the multi-well

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plate (24) (see FIGS. 11-13). Such attachment means (184), which are extending from and in the same planar relationship as the lid (154), function as stacking lugs, as the cover (15) is stacked on the multi-well plate (24) (see FIGS. 11-13). The geometrical relationship of the stacking lugs, as defined by the sidewalls and/or attachment means, and stacking locators, as defined by the projections and apertures of the top surface of the lid (154), is such that a cover can be aligned vertically upon another cover in a stacked relationship (see FIGS. 11-13). It is noted that method limitations, such as function as stacking lugs, in device claims have no patentable weight in device claims if the prior art apparatus teaches all the structural limitations of the claim (MPEP 2114).

In the process of securing the lid (154) to the multi-well plate (24), the side walls of the lid (154) cause deformation of the curvilinear section of the lid (154), resulting in a normal spring force applied to the gasket (156) and compressing the gasket (156) against the upper planar surface of the multi-well plate (24) via the means (184), which is part of the side walls of the lid, extending past the perimeter skirt (24a) of the multi-well plate (24) and engaging the bottom of the skirt to effect a seal between the gasket (156) and wells of the multi-well plate (24) (see FIGS. 11-13; COL. 27, lines 66 and 67; COL. 28, lines 1-17 and 43-67). The occurrence of deformation and application of normal spring force is inherent to the structure. It is noted that method limitations in device claims have no patentable weight in device claims if the prior art apparatus teaches all the structural limitations of the claim (MPEP 2114).

Therefore, Moring et al. include all the limitations in claims 1-3, 5-7.

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Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 2 (alternatively), 3 (alternatively), 5 (alternatively), 6 (alternatively) rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,159,368 to Moring et al. in view of U.S. Patent No. 6,486,401 to Warhurst et al.

Referring to claim 2, Moring et al. do not explicitly disclose about four of the projections **function as notched tabs with locator holes** for gripping of the cover by mechanical methods. Warhurst et al. disclose four projections in the form of tabs (29) with outer notches (42) and beveled bottom edges for gripping by mechanical methods (see FIGS. 2, 3A, 3B, and 5; COL. 4, lines 21-27). Since the drawings in the immediate application point to the tabs with notches as locator holes, locator holes has been interpreted as the term or label for the combination of tabs with notches. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moring et al. to include tabs with outer notches (42) and beveled bottom edges as in Warhurst et al. to aid in robotic gripping.

Referring to claims 3 and 5, Moring et al. do not explicitly disclose that at least two of the projections extend from and in the same planar relationship as the side walls of the lid and function as stacking lugs. Warhurst et al. disclose that side walls of the lid extend into projecting ridges or stacking lugs on the top surface of the lid with clearance notches (32) or stacking locators in a geometrical relationship affording vertical alignment of one cover upon another (see FIGS. 3A and 4). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moring et al. to provide stacking lugs and locators as in Warhurst et al. to vertically align the covers upon covers.

Referring to claim 6, Moring et al. do not explicitly disclose that each of the side walls has a formed element distal to the curvilinear section for holding

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the multi-well plate. Warhurst et al. disclose that the side walls have a formed element (25) distal to the curvilinear section serving to hold the multi-well plate (see FIGS. 3A, 3B, 4; COL. 3, lines 25-30; COL. 4, lines 16-20). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moring et al. to include a formed element distal to the curvilinear section as in Warhurst et al. to hold the multi-well plate.

20. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,159,368 to Moring et al. in view of U.S. Patent No. 2,825,466 to Shnitzler et al.

Referring to claims 3-5, Moring et al. do not explicitly disclose stacking lugs and locators. Shnitzler et al. disclose stacking lugs in the form of projections extending from and in the same plane as the side walls and stacking locators in the form of apertures in the 90 degree bend between the side wall and curvilinear for compactly stack covers and plates vertically (see FIGS. 1 and 2; COL. 1, lines 15-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moring et al. to include stacking lugs and locators as in Shnitzler et al. to compactly and attractively stack covers upon covers.

21. Alternatively, claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,159,368 to Moring et al. in view of U.S. Patent No. 6,426,050 to Pham et al. or U.S. Patent No. 6,254,833 to Shumate et al. or U.S. Patent No. 6,361,746 to Wlodarski.

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Referring to claim 4, Moring et al. do not disclose at least two of the apertures formed in the 90 degree bend between the side wall and curvilinear section. However, Shumate et al. and Pham et al. and Wlodarski all show at least two apertures formed in the 90 degree bend between the side wall and curvilinear section to facilitate stacking or enable viewing of contents enclosed by the lid. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moring et al. to include at least two apertures in the 90 degree bend between the side wall and curvilinear section as in Pham et al. or Shumate et al. or Wlodarski to facilitate stacking and/or enable viewing of contents enclosed by the lid.

22. Alternatively, claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,159,368 to Moring et al.

Referring to claim 7, Moring et al. do not explicitly disclose that the gasket material has a durometer of Shore 15A or less and low extractables in dimethyl sulfoxide. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moring et al. to make the gasket from a material having a durometer of Shore 15A or less and low extractables in dimethyl sulfoxide in order to provide a desired degree of flexibility sufficient to seal the wells of a multi-well plate.

23. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,159,368 to Moring et al. in view of U.S. Patent No. 6,379,626 to Munson et al. and U.S. Patent No. 6,103,199 to Bjornson et al.

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Referring to claim 8, Moring et al. do not disclose that the lid is made from steel, spring steel, or stainless steel. However, Munson et al. disclose that the cover is made from stainless steel for corrosion resistance (see COL. 2, lines 59-61). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moring et al. to make the cover from stainless steel as in Munson et al. to prevent corrosion.

Moring et al. do not address the thickness of the cover. However, Bjornson et al. disclose that cover thicknesses are more usually at least about 500 micrometers or 0.019685039370079 inches, which is within the recited range, as required for different materials with different mechanical properties (see COL. 25, lines 65-67; COL. 26, line 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moring et al. to provide a cover thickness between 0.015" and 0.024" as in Bjornson et al. to obtain a cover exhibiting certain properties to create an effective seal with the multi-well plate.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for


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the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

eq
March 5, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700